DORA Trial

A phase I and randomised phase II study of docetaxel and RAD001 (Everolimus) in advanced/recurrent or metastatic squamous cell carcinoma of the head and neck

Clinical Study Report

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EudraCT Number	2007-001951-20
Sponsor	University College London
Sponsorship Number	UCL/06/053
Chief Investigator	Prof Chris Boshoff
Sponsor contact	Marian Duggan
	Trial Coordinator
	CR UK & UCL Cancer Trials Centre
	90 Tottenham Court Road
	London, W1t 4TJ
Contact details	Tel 020 7679 9883
	Fax 020 7679 9871
	Email: dora@ctc.ucl.ac.uk

IMPs	RAD001, Docetaxel
Indication	Patients with advanced/recurrent or metastatic squamous cell carcinoma of the head and neck.
Treatment:	**Phase I** • RAD001 (everolimus) dose escalation (10-50mg) and docetaxel 75mg/m^2 **Phase II** • Arm A - docetaxel 75mg/m^2 • Arm B – docetaxel 75mg/m^2 + RAD001 (everolimus)
Start date:	03/06/2009
End date	21/04/2011 (Please note trial was suspended from recruitment for approximately six months between March –August 2010 due to urgent safety measure).

Objectives	**Phase I Objectives:**
	• <u>Primary objective:</u>
	  • To determine the safety and tolerability of the combination of RAD001 (everolimus) and docetaxel
	  • To determine the maximum tolerated dose of RAD001 (everolimus) when combined with docetaxel
	• <u>Secondary objectives:</u>
	  • To investigate possible pharmacokinetic interactions between Docetaxel and RAD001 (everolimus)
	  • To investigate the effect of RAD001 (everolimus) on downstream targets of mTOR in tumour
	
	Phase II Objectives:
	• <u>Primary objective:</u>
	  o To examine the response rates in patients receiving the combination of docetaxel and RAD001 (everolimus) and those receiving docetaxel alone.
	• <u>Secondary objectives:</u>
	  o To examine the time to progression after docetaxel and RAD001 (everolimus).
	  o To perform a pilot study to attempt to identify predictors of response including evaluation of EGFR family member expression, mutations or amplifications. Also downstream targets of the EGFR pathway including phosphorylation of S6 and phosphorylation of AKT.

Justification of premature ending of trial:	The phase I of the DORA trial was open to recruitment for a total of 18 months and recruited 4 patients during this time point. Two patients had to be replaced due to ineligibility and the cohort was re-open to a further three patients. However only two patients were recruited in the cohort and the decision was made to close the trial due to lack of recruitment.
Number of patients still receiving treatment at termination	0

Proposed management of patients receiving treatment at time of termination:	N/A
Study achieved its objective?	No, due to low recruitment numbers it was not possible to evaluate any trial endpoints of the phase I trial. The phase II trial did not open to recruitment.
Main findings	N/A
Arrangement for publications	There will be no publications for this trial.
Arrangements for dissemination of the research, including any feedback to participants.	N/A